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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/549,623

09/20/2005

Hiroyuki Sugawara

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EXAMINER

CECIL, TERRY K

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

03/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

|                              |                                       |  |  |
|------------------------------|---------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/549,623  | <b>Applicant(s)</b><br>SUGAWARA ET AL. |  |
|                              | <b>Examiner</b><br>Mr. Terry K. Cecil | <b>Art Unit</b><br>1797                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9-20-2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-20-2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION*****Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

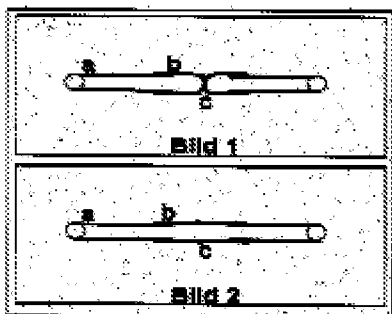
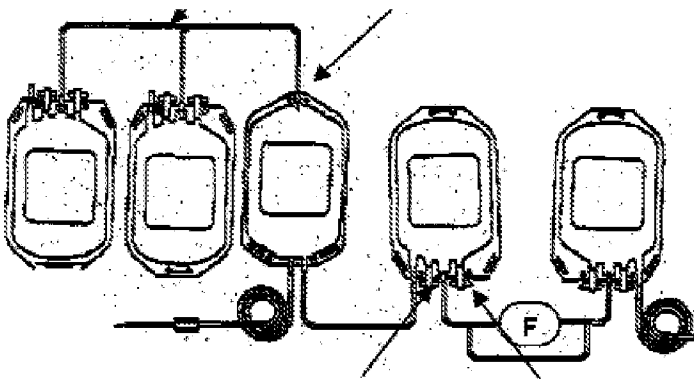
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by

DE10019985A1, hereinafter '985.



'985 teaches a blood treating set including a blood collecting device including at least one bag (center bag) and a blood treating device including a plurality of bags (at least the two bags on the right) for centrifuging. The tubes

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connecting the bags are interconnected at elements b and c that indicate the connecting region between tubes [as in claims 1-2 and 6]. After connection (lower portion of the figure), the length of the tubes is constant [as in claim 3]. The blood treatment device is operative to separate the blood components by centrifugation (abstract) [as in claim 7].

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

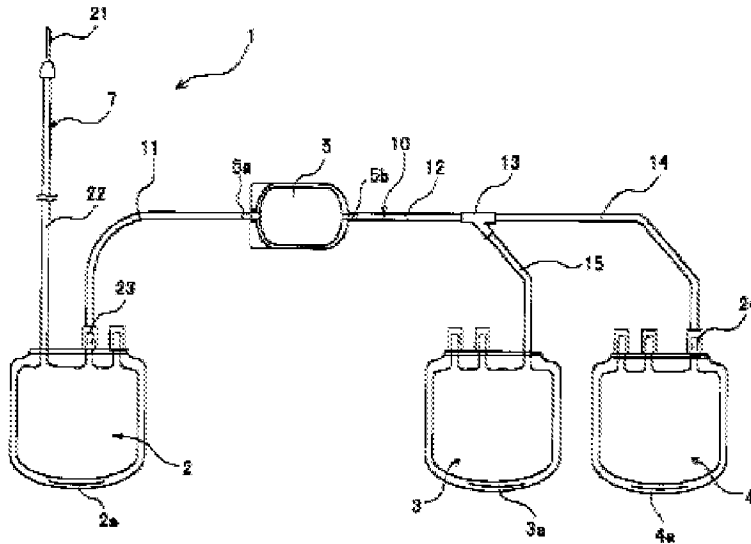
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

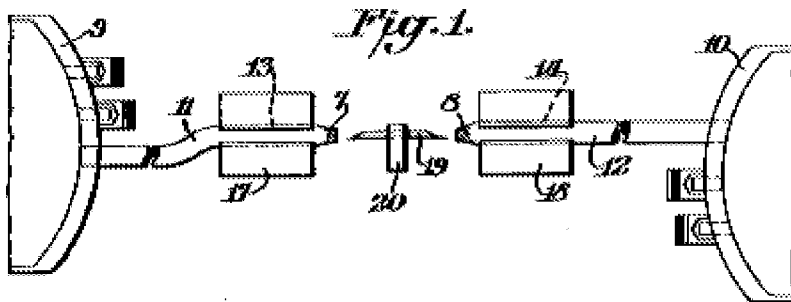
4. Claims 4-5 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over '985. As shown in his drawings, '985 teaches a leukocyte removing filter "F". These claims differ in that they require the filter to be "midway" of the first or second tube. The precise location of the filter in the tube is insufficient for patentability and would have been obvious depending upon the environment the device will be used and the length of tube necessary for the particular application of use.

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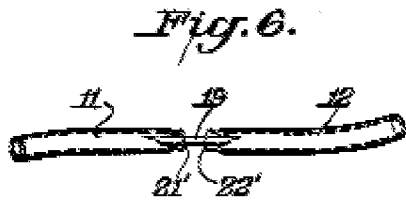
5. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2001-276212, hereinafter '212 in view of Smith (U.S. 4, 443,215).



'212 teaches a blood or cell treating set including a blood collecting device having a collection bag 2 and a first tube extending therefrom; a centrifugal blood treatment device including a plurality of bags 3, 4 for storing blood components; and a leukocyte-removing filter 5. '212 doesn't explicitly teaching the indication for indicating a connection position or the reduced diameter portion.



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Smith teaches a connection area between bags that includes an “indication” (the groove near 21’, 22’) within the reduced diameter area 21’, 22’. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the connection area in the lines between bags (e.g. lines 11, 12) since Smith teaches the benefit of connecting bags for transfer of fluid that is sterile. As for the limitation of the filter being “midway”, the precise location of the filter in the tubes is considered to be within ordinary skill (as stated above). As for claims 8, 9 and 10, the steps of forming the reduced diameter portion including the step of mounting in a tube connecting device are considered to be product-by-process limitations.

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777

F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). It is contended that Smith teaches the claimed indication and reduced diameter structure. Any difference is considered to have been obvious.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Terry K. Cecil whose telephone number is (571) 272-1138.

The examiner can normally be reached on 8:00a-4:30p M-F..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mr. Terry K. Cecil/  
Primary Examiner, Art Unit 1797

tkc